K110260

Special 510(k) Summary
for
NewTom 5G Computed Tomography X-Ray System

1. 510(K) SUBMITTER/MANUFACTURER

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APR - 6 2011

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2. DEVICE NAME

Proprietary Name:	NewTom 5G
Other Model Name:	NewTom 5G version FP
Common/Classification Name:	Computed Tomography X-Ray System

3. PREDICATE DEVICES

NewTom VG Computed Tomography X-Ray System K072357

4. DEVICE DESCRIPTION

The NewTom 5G is a dedicated X-ray imaging device that acquires a 360-degree rotational X-ray sequence of images. It reconstructs a three-dimensional matrix of the examined volume and produces two-dimensional views of such volume, displaying both two- and three-dimensional images. The NewTom 5G can measure distances and thickness on two-dimensional images. Such images can be printed or exported on magnetic and optical media.

The NewTom 5G is designed for use in diagnostic support both in dento-maxillo-facial radiology, with a particular reference to "planning" and to monitoring of implantations and in the field of maxillofacial surgery.

The NewTom 5G hardware, including a scanner unit (comprised of the X-ray source, flat panel detector and the motorized arm) and a motorized patient support, facilitates the acquisition of a full X-ray sequence by the device software. The NewTom 5G software runs on an x86 architecture based workstation. The NewTom 5G reconstructs a three-dimensional model of X-ray images similar to the three-dimensional model obtained using the parent NewTom VG Computed Tomography X-Ray System.

5. INTENDED USE

The NewTom 5G is a dedicated X-ray imaging device that acquires a 360-degree rotational X-ray sequence of images for use as diagnostic support in radiology of the dento-maxillo-facial complex and in the field of maxillofacial surgery. The NewTom 5G accomplishes this task by reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume and displaying both two-dimensional images and three-dimensional renderings.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of the NewTom 5G computed tomography X-ray system and the parent NewTom VG Computed Tomography X-Ray System are substantially equivalent since they are devices designed to provide images for use as diagnostic support in radiology of the dento-maxillo-facial complex and in the field of maxillofacial surgery. The proposed NewTom 5G and the parent NewTom VG are computer controlled dedicated X-ray imaging devices that construct three-dimensional models from images taken during a rotational X-ray sequence. It is optimized for bone morphology analysis of the maxillofacial region.

The proposed NewTom 5G and the NewTom VG both use an X-ray imaging system that acquires a 360 degrees rotational X-ray sequence and reconstructs a three-dimensional matrix of the examined volume and produces two-dimensional views of this volume, displaying both two- and three-dimensional images.

The proposed NewTom 5G hardware includes a scanner unit and a motorized patient support whereas the parent NewTom VG system consists of the same components of the scanner unit (X-ray source, flat panel detector and motorized arm) with a different

patient support. The proposed NewTom 5G allows imaging to be performed in a supine position and the parent NewTom VG system only allows imaging to be performed in sitting and standing position. The above differences do not impact safety or effectiveness since both the parent NewTom VG and the proposed NewTom 5G system are identical in that they are computer controlled dedicated X-ray imaging devices that constructs three-dimensional models from images taken during a rotational X-ray sequence. The technological characteristics for both the proposed NewTom 5G and the parent NewTom VG devices provide the user with a method of constructing a three-dimensional models from images taken during a rotational X-ray sequence. Therefore, hardware and software modification to support the new ergonomics and to improve image quality and reliability represent minor technological differences that do not affect the overall safety or effectiveness of the proposed NewTom 5G Computed Tomography X-ray System.

7. PERFORMANCE TESTING

Electrical safety, EMC/EMI testing, and verification and validation testing were performed to support the hardware and software modifications. The NewTom 5G computed tomography X-ray system met all requirements, and functioned as intended and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 23 2013

Mr. Lorenzo Bortolotti
Quality and Regulatory Affairs Manager
QR srl
Via Silvestrini 20
VERONA 37135
ITALY

Re: K110260
Trade/Device Name: NewTom 5G
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: February 28, 2011
Received: March 10, 2011

Dear Mr. Bortolotti:

This letter corrects our substantially equivalent letter of April 6, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

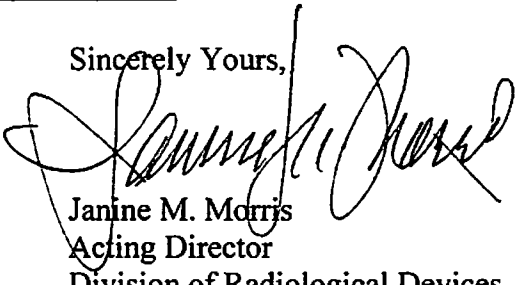
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: NewTom 5G

Indications for Use:

The NewTom 5G Computed Tomography X-Ray System is a dedicated X-ray imaging device that acquires a 360-degree rotational X-ray sequence of images for use as diagnostic support in radiology of the dento-maxillo-facial complex and in the field of maxillofacial surgery.

The NewTom 5G accomplishes this task by reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume and displaying both two-dimensional images and three-dimensional renderings.

Prescription Use __X__ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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